



ARIZONA STATE BOARD OF PHARMACY

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Documents Management Branch
Food and Drug Administration
(HFA-305), Room 1061
5630 Fishers Lane
Rockville, MD 20852

June 1, 1999

SUBJECT: Docket Number 98N-I265
Federal/State Memorandum of Understanding on Interstate Distribution of
Compounded Drug Products

To Whom It May Concern:

Pursuant to publication of proposed *Memorandum of Understanding on Interstate Distribution of Compounded Drug Products*, (MOU) and opportunity to comment, the Arizona State Board of Pharmacy (Board) petitions the Food and Drug Administration (FDA) to extend the comment period in the above cited matter for the following reasons.

- ▶ Our agency requests that FDA extend the period of open comment in the above referenced matter until August 1, 1999.
- ▶ Our agency petitions FDA to consider the impact on the practice of medicine and the impact on patients that rely on the expertise of the community pharmacist in custom compounding prescriptions pursuant to the prescription of a licensed medical practitioner.
- ▶ The Arizona Board of Pharmacy appreciates the agency willingness to conduct open comment and discussion sessions at major pharmacy association(s) meetings. Such an effort on FDA's part demonstrates a sincere attitude and willingness to solicit comment and constructive recommendations on a significant public policy change.
- ▶ The Arizona Board of Pharmacy encourages FDA to reconsider the implementation of any professional practice altering rule or regulation until every possible option has been exhausted. The board submits that through routine inspections of every pharmacy in the state, compounding pharmacies are evaluated and remediated where needed for the protection of the public health.
- ▶ Regardless of agreements and formal MOU's, 'fringe operators' will seek opportunities to flaunt the letter and the intent of a regulatory provision; while legitimate professional pharmacists will look for opportunities to serve their patient's pharmacy health care needs. Arizona Board of Pharmacy invites FDA to partner with state boards of pharmacy in addressing the non-compliant pharmacies in any state or jurisdiction
- ▶ The Arizona Board of Pharmacy is authorized (and willing) to investigate and adjudicate pharmacy operators that jeopardize the public health and welfare. The Patient-Physician-Pharmacist relationship is critical to protecting the public health and we demand that pharmacists observe these regulations.

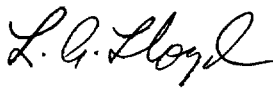
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In addition to the petition for extension of the comment period, the Arizona Board of Pharmacy submits the following observations, comments and suggestions for consideration should there be a revision of the 'DRAFT MOU':

- ▶ Consider the impact of severely restricting compounded prescriptions that are allowed to be delivered interstate. Professional pharmacists, focusing on custom compounding of prescriptions are a valuable health resource. Many of today's sophisticated consumers rely on well trained pharmacists to custom compound prescriptions; restricting the delivery of these items will adversely impact public health.
- ▶ Aggressive compliance/enforcement efforts to control or eliminate "unprofessional" and blatantly non-compliant "pharmacies" from continuing unacceptable business practices...with the assistance of a local board of pharmacy, would seem more reasonable and more productive in terms of protecting the public health than imposing unrealistic restrictions on interstate distribution of valid compounded prescriptions.
- ▶ Based on nearly twenty years of service with the state board of pharmacy and in joint compliance efforts with the Food and Drug Administration; it has been our impression that boards of pharmacy provide a valuable resource to FDA relevant to pharmacy practice compliance issues. Our board hopes to continue as a resource to FDA in issues involving pharmacy practice concerns with the potential to impact the public health and safety. We believe that "partnerships" of FDA and boards of pharmacy provide a valuable health protection function.

THE ARIZONA STATE BOARD OF PHARMACY
by:



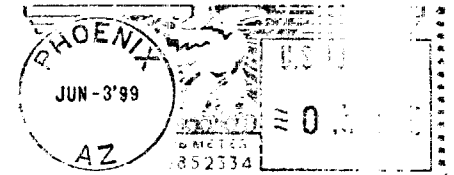
L. A. Lloyd, R. Ph.
Executive Director



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